

### UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO		
09/655,710	09/05/2000	Suman Preet Singh Khanuja	056859/0107 8287			
7	590 10/21/2002					
Bernhard D. Saxe FOLEY & LARDNER Washington Harbour 3000 K Street, N.W., Suite 500 Washington, DC 20007-5109			EXAMINER			
			COE, SUSAN D			
			ART UNIT	PAPER NUMBER		
admington, D	2000, 2.09		1654	1654		
			DATE MAILED: 10/21/2002 /8			

Please find below and/or attached an Office communication concerning this application or proceeding.

	FILE COPY								
****		Applicati n	Ν.		Applicant(s)				
11		09/655,710			KHANUJA ET AL.				
1	Office Action Summary	Examiner			Art Unit				
		Susan Coe			1654				
	The MAILING DATE f this communication ap	pears on the c	over s	heet with the c	rrespondence ad	Idress			
Period for Reply									
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).									
Status 1)⊠	Responsive to communication(s) filed on 15	August 2002	•						
2a)□	OLIVI This petion is non-final								
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.									
•	on of Claims								
4)⊠ Claim(s) <u>1-48</u> is/are pending in the application.									
4a) Of the above claim(s) 7,8,11-26 and 28-48 is/are withdrawn from consideration.									
5) Claim(s) is/are allowed.									
6)⊠ Claim(s) <u>1-6,9,10 and 27</u> is/are rejected.									
7) Claim(s) is/are objected to.									
8) Claim(s) are subject to restriction and/or election requirement.									
Application Papers									
9) The specification is objected to by the Examiner.									
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.									
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.									
11) The proposed drawing correction filed on is. a) approved by disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.									
12) The oath or declaration is objected to by the Examiner.									
Priority under 35 U.S.C. §§ 119 and 120									
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).									
a) All b) Some * c) None of:									
1. Certified copies of the priority documents have been received.									
	The second of th								
2. Certified copies of the priority documents have been received in Application 70.  3. Copies of the certified copies of the priority documents have been received in this National Stage									
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.									
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).									
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.									
Attachment(s)									
1)  Noti	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	)	5) 🔲	Interview Summa Notice of Informal Other: .	y (PTO-413) Paper N Patent Application (F	No(s). <u>14 &amp; 15</u> . PTO-152)			

Application/Control Number: 09/655,710

Art Unit: 1654

#### **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 15, 2002 has been entered.
- 2. Claims 1-48 are pending. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
- 3. Claims 7, 8, 11-26, and 28-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7.
- 4. Claims 1-6, 9, 10, and 27 are examined on the merits.

# Claim Rejections - 35 USC § 112

5. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 specifies that the concentration of glycyrrhizin can be up to 50% by weight of the anti-bacterial compounds. This limitation seems in conflict with the limitation in claim 1 that states that the glycyrrhizin component cannot be present in a pharmaceutically effective amount. It is unclear how the component can be present in such as high concentration and not be pharmaceutically effective.

Application/Control Number: 09/655,710

Art Unit: 1654

### Claim Rejections - 35 USC § 102

6. Claims 1-5 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,939,050 for the reasons set forth on page 3 of the Office action of December 18, 2001.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that US '050 does not teach adding the glycyrrhiza extract in amounts that are not therapeutically effective. However, applicant's specification defines a non-therapeutically effective amount of Glycyrrhiza glabra extracts to be either 1 ug/ml, 4 ug/ml, or 25 ug/ml (see pages 14, 16, and 19). US '050 teaches adding the Glycyrrhiza extracts in these amounts (see column 11, Table 6). Therefore, based on what applicant has defined as the proper amount of extract to add, US '050 is still considered to meet the limitations of the claims.

## Claim Rejections - 35 USC § 103

7. Claims 1, 5, 6, 9, 10, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,939,050, The Merck Index (Budavari et al. (eds) (1989), 11<sup>th</sup> edition, Merck & CO., Inc: New Jersey, entry numbers 2315, 6273, and 6617) and US Pat. No. 5,478,829 for the reasons set forth on page 5 the Office action of December 15, 2002.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant against this rejection for the same reasons as for the US '050 102 rejection. However, since US '050 is still considered to teach the claimed invention, this rejection is still considered valid for the reasons of record.

Application/Control Number: 09/655,710

Art Unit: 1654

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC October 10, 2002

LEON B. LANKFORD, JR. PRIMARY EXAMINER